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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/711,078

08/20/2004

Stanley Charles Antosh

5077

45383 7590 07/24/2007  
OSMO, INC.  
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EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1609

MAIL DATE

DELIVERY MODE

07/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/711,078

**Applicant(s)**

ANTOSH ET AL.

**Examiner**

Samira Jean-Louis

**Art Unit**

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____                                                           | 6) <input type="checkbox"/> Other: ____                           |

### ***Objections***

The abstract of the disclosure is objected to because it contains legal phraseology such as "comprising" in line 1. In addition, the abstract should commence on a separate sheet under the heading "Abstract" (i.e. without any title on the abstract page). Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 1-12 are rejected under 35 U.S.C. 112, second paragraph because they are indefinite in that they fail to point out what is included or excluded in the vitamins, minerals and amino acids group as stated by the claim language in claims 1, 5 and 9. Applicant stated that the composition entails vitamins, minerals **and** amino acids selected from the group consisting of: pyridoxal-5-phosphate, nicotinic acid, copper, 3-aminopropionic acid (beta alanine), histidine, alpha lipoic acid, carnosine; however, the aforementioned group entails several vitamins, 1 mineral (i.e. copper) and several amino acids. Furthermore, claims also include alpha lipoic acid, which is considered to be an antioxidant, and consequently not part of the above said group.

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Thus, the language form of the claims is vague and indefinite. For the purpose of examination; however, the claims were construed to mean that the transdermal liquid composition entails methyl nicotinate with vitamins, minerals and amino acids.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In addition, this application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C 103 (a) as being unpatentable over Brown et al. (Pub. Date 2003) in view of Burnett et al. (Pub. Date August 12, 2004).

Brown et al. teaches a basic topical therapeutic application comprising an aqueous solution of copper with additional substances such as a vasodilators, vitamins and amino acids associated with a skin and tissue-penetration enabler. In particular, Brown et al. teaches a "basic therapeutic unit" made of **1% copper** (which is a mineral as in claim 1-line 6) and a carrier that is suitable for topical application (see Detailed Description, paragraph 0012, lines 3-6 and paragraph 0022, table). Furthermore, Brown et al. teaches that this copper basic therapeutic unit formulation may further be enhanced by a vasodilator such as .3% methyl nicotinate (as in claim 1 line 2) and by additional substances including 2.5% polysorbate-80 (instant claim 2) and water (instant claim 3), all which are components of applicant's invention (see paragraph 0022-table). Although Brown et al. did not specifically disclose specific vitamins and amino acids in their invention; they did however list granular soy lecithin (see paragraph 0017, line 3), which is composed of soy flour mixed lecithin (see [www.bulkfoods.com/lecithin.htm](http://www.bulkfoods.com/lecithin.htm)). Soy flour in itself is well known in the art to be highly enriched in proteins (i.e. amino acids-histidine and alanine –see Iwe et al. 2001, table 2) and vitamin B3 or niacin or nicotinic acid ([www.soyfoods.com](http://www.soyfoods.com)). In addition, the lecithin content disclosed in Brown et al. is present in low percentage (see paragraph 0022) and consequently is reasonably considered to be the part of said lecithin formulation (paragraph 0022) therein given as the granular soy lecithin listed in paragraph 0017. Therefore, it can reasonably be concluded that the aforementioned lecithin contribution of amino acids and vitamins from the formulation (see paragraph 0022) is reasonably small and would

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represent a small percentage by weight to the formulation in Brown et al. thus suggesting the low percentage by weight in applicant's claim 1 (instant claim 1) comprising the combination of vitamins, minerals and amino acids.

Thus, Brown et al. teaches a topical application with its approximate weight percentages comprising .3% methyl nicotinate, 1% copper gluconate, 1.5% lecithin, 2.5% polysorbate-80 and 71.1% water and provides the requisite excipients as recited in claims 1-12.

Brown et al. does not teach said liquid application comprising of alcohol as recited in claims 4, 8 and 12. However, Burnett et al. discloses that topical composition for topical delivery can comprise a penetration enhancer or solvent such as alcohol (see Summary of the Invention, paragraph 0009-section A).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to take the alcohol from Burnett et al. and add it to the composition of Brown et al. given that Brown essentially teaches a topical application made up of methyl nicotinate with vitamins, copper and amino acids and Burnett et al. teaches that alcohol can be used as a penetration enhancer for topical composition delivery.

Consequently, one of ordinary skill in the art would have been motivated to add the alcohol enhancer of Burnett et al. to the composition of Brown et al. with a reasonable expectation of success.

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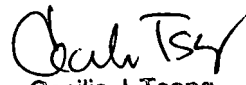
### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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Supervisory Patent Examiner  
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